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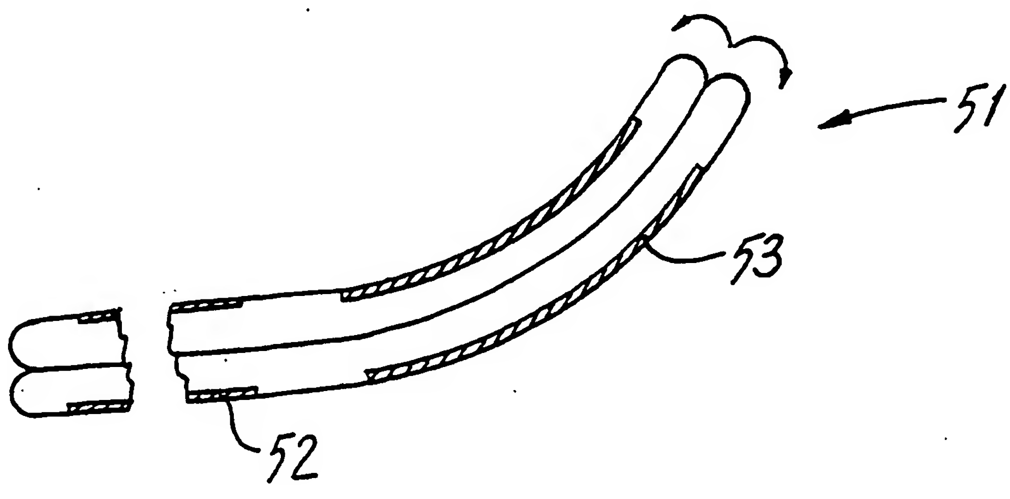
(54) Title: A MEDICAL DEVICE COMPRISING AN EVERTABLE SLEEVE




(57) Abstract

A medical device may comprise an introducer (1) for introducing an object such as an instrument through a body opening such as the throat. The device (1) comprises a tubular sleeve (10) of pliable plastics material which is turned axially back on itself to define inner an outer sleeves sections (11, 12). The inner sleeve section (11) defines an inner lumen (19) and the sleeve may be twisted to centralise the lumen. The sleeve is pre-shaped to define a desired non-linear shape. A chamber (16) between the inner and outer sleeve section (11, 12) is inflatable. The device may also be deployed remotely for example, for balloon angioplasty.

# A MEDICAL DEVICE COMPRISING AN EVERTABLE SLEEVE

## Introduction

The invention relates to a medical device, particularly for use in minimally invasive and endoluminal surgical and medical techniques. In particular the invention relates to an introducer for introducing an instrument into the body through an opening. More specifically, the invention relates to a device to assist in the introduction of endoscopic devices into the lumen of a natural bodily orifice, in particular the rectum and colon.

The introduction of an instrument or the like through a body opening such as the throat or rectum is traumatic for the patient and difficult for the medical practitioner as such openings lead into a complex passageway(s) through which the instruments must be passed. Therefore great skill and experience is required.

## Background of the Invention.

The practise of gastroenterology has been much improved due to the development of the fibre-optic endoscope. Modern endoscopes consist of a control section attached to a long flexible shaft with a steerable tip. The flexible shaft carries several tubes for light, air, water and suction. In some cases a biopsy channel with a larger bore to allow therapeutic procedures to be performed is included. Light is transmitted through non-coherent fibre-optic bundles. Older scopes used coherent fibre-optic bundles for transmission of the image but these are largely obsolete now and video-endoscopes are the norm. These use fibre-optic bundles for light transmission only and use a CCD TV camera for image acquisition. The camera output is then transmitted through wire pairs.

Endoscopes use a torque control mechanism that allows the endoscope to be steered through the passage of interest using control wheels on the handle at the

through simply because of their tortuous nature. Problems traversing these areas are exacerbated by looping of the endoscope in the sigmoid colon.

Endoscopy is a difficult technique that can only be mastered after performing many hundreds of examinations. The ability to speedily cannulate the bowel and traverse the entire colon all the way to the caecum is a skill that is only enjoyed by a minority of endoscopists. Published research on the subject of difficulty encountered in endoscopy shows that the procedure fails in up to 15% of cases where failure is defined as inability to reach or visualise the caecum. Up to 35% of cases are considered to be difficult as defined by extended duration of the procedure and experience of pain by the patient. Other research shows that up to 29% of cases are considered to be technically difficult.

Several devices have been described in the prior art to assist in the practise of lower GI endoscopy.

US-A-3805770 describes an endoscope guide and lubricating means comprising a cylindrical spongy member to guide and lubricate the endoscope as it enters the anus. This device however does not address the problems associated with looping of the scope in the sigmoid colon and resulting problems crossing the splenic and hepatic flexures.

US-A-4207872 describes a sleeve device for positioning on the end of an endoscope to assist it in advancing through a body passage. The device has protrusions extending perpendicularly from the sleeve that may be expanded and retracted using fluid pressure. Upon repetitious expansion and retraction of the protrusions using pulsing pressure within the device, the device assists in advancing the scope along the body passage. There is likely to be considerable internal friction between the device and the inner wall of the body passage.

advanced through a duct such as the human colon. WO-A-99/01171 describes a similar device with the addition of corrugations designed to assist in the passage of the endless tube around the anatomy of the colon.

US-A-5941815 describes a sigmoid splint device for use in endoscopy. The device is intended to be used to keep the sigmoid colon from looping while the operator is attempting to cross more difficult junctions.

In general, such known devices are either difficult to use, cause discomfort to the patient, can only be advanced incrementally, do not cater for complex nature and shape of tortuous body passageways.

There is a need for an improved medical device which will address at least some of these problems and which may be especially used as an introducer to navigate the lower gastrointestinal tract with minimum discomfort to the patient.

Statements of Invention

According to the invention there is provided a medical device for insertion in a body opening or an incision comprising:-

a sleeve of pliable material having an outer sleeve section and an inner sleeve section;

a chamber for pressurised fluid defined between the inner and outer sleeve sections;

the inner sleeve section defining a lumen to receive an object;

the sleeve being evertable on engagement of an object in the lumen and axial movement of an object relative thereto so that the inner sleeve section

In one embodiment of the invention the devices includes guide means through which the sleeve and/or an object is advanced.

The guide means may include a ring means for placing in a body opening or incision through which the sleeve and/or an object is advanced.

In one embodiment of the invention the device includes a delivery means for delivery of the device to a remote location.

The delivery means may be a tube such as a catheter or a cannula.

In one aspect the device defines a transporter for delivery or retrieval of an object to or from a desired location.

In another aspect the device defines an introducer for introducing an object such as an instrument to a desired location.

In a further aspect the device is an expandable element such as a balloon for example for angioplasty.

Brief Description of Drawings

The invention will be more clearly understood from the following description thereof given by way of example only, in which :-

Fig. 1 is a perspective view from a proximal end of an introducer according to the invention.

Fig. 2 is a perspective view from a a distal end of the introducer of Fig. 1;

Fig. 3 is a cross sectional view of the introducer in one position of use;

Fig. 31 is a plan view of the device of Fig. 30; and

Fig. 32 is a cross sectional view on the line B-B in Fig. 31.

## Detailed Description

Referring initially to Figs 1 to 7 there is illustrated a medical device according to the invention which in this case is configured as an introducer 1 for introducing an object such as an instrument through a body opening such as the throat or rectum.

The device 1 comprises an elongate tubular sleeve 10 of pliable material, especially a suitable biocompatible gas impermeable plastics material which is turned axially back on itself to define an inner sleeve section 11 and an outer sleeve section 12. The sleeve sections 11, 12 are joined in this case via a collar 15, to define an enclosed inflatable chamber 16 therebetween. The inner sleeve section 11 defines an inner lumen 19 and the sleeve is twisted to centralise the lumen 19. An inflation port 20 is provided for inflating the chamber 16 between the inner and outer sleeve sections.

It will be particularly apparent that the device of the invention may be readily advanced through a complex passageway such as the bowel or the like. It may therefore be used for cannulating such a passageway.

Figs 6 and 7 illustrate the twisting of the sleeve 10. The free ends of the sleeve 10 are rotated relative to one another prior to or after final assembly to the collar 15. The twist will be apparent with reference to the points marked X. Such a twist may be provided when the device is in situ and is adjustable in situ.

The present invention provides a device that permits an endoscope or similar instrument to pass easily through the body's natural canals for purposes of

colon or turn at the splenic flexure as it moves through the colon. The device may be predisposed to bend at more than one point. For example, it could be constructed in such a manner that it would gradually curve through the sigmoid colon and then straighten out to traverse the descending colon. A further turn could be constructed into the device so that it would turn at the splenic flexure. By preshaping the everting tube in this manner it would be possible to plan all the bends and convolutions in a passageway to be navigated.

The device may be used as a transporter for delivery or retrieval of an object. It has the effect of providing a substantially frictionless tunneling action. The device may be used endoluminally. The device may be used for example to provide a soft tissue dissector or an envaginator and may be delivered through a delivery device such as a tubular sleeve, catheter or the like. The device itself may be used in medical procedures such as in the form of a balloon which may be linear or non linear.

Referring to Figs 10 to 16 there is illustrated a device 60 similar to that of Figs 1 to 7 which is deliverable through a tube 6 such as a cannula. A pressure is applied to push the device 61 out through an end opening of the tube 61 as illustrated in Figs 10 to 12. To retract the device a suction force is applied to draw the device 60 back into the tube 61 as illustrated in Figs 13 and 14.

Referring in particular to Figs 15 and 16 there is illustrated one mechanism which may be used to deliver the device 60 through the tube 61 and to remotely control the operation of the device 60. Air is delivered through an air delivery tube 65 extending through the outer tube 61. The air delivery tube 65 has a central outlet 66 for driving the device 60 and one or more entry ports 67 for delivery of inflation air into the air chamber 69 defined by the device 60. In this way the inflation of the device 60 can be readily remotely controlled. The device 60 may

Elongate object passed through twisted tube

As can be clearly seen from Figs 18a and 18b the angle of twist necessary to collapse the lumen of a tube to the diameter of an elongate object passed therethrough is dependant on the ratio of the tube diameter and the diameter of the elongate object. The angle of twist can be calculated from:

$$\mathrm{Cos.}^{-1}(E/2) = D2/D1$$

Where E = angle of twist

D1 = tube diameter

D2 = diameter of elongate object

Although depicted as of circular profile, a tube of sufficiently compliant material will conform to any non recursive profile. For such a profile D2 is taken as the smallest diameter which can be inscribed within the profile.

Twin walled pressure vessels under internal pressure

Consider a thin walled tube as shown in Fig. 19a. One end of the tube is folded back on itself as shown in Fig. 19b and the fee ends conjoined. What is defined is essentially a twin walled tube (or two coaxial tubes conjoined at their ends) with an enclosed volume between the two walls. The introduction of a pressurised fluid into the enclosed volume will cause the outer tube to behave like a pressurised aircraft fuselage, that is it will be subject to tensile axial and hoop stresses. The inner tube will be subject to tensile axial stress and compressive hoop stress. As a result the lumen will collapse in to a nominally duck bill configuration but constrained by the outer tube.

contact A, between the Cyclops and the fixed surface, and B, between the shaft and the lumen of the Cyclops. As the shaft is translated, as shown in Fig. 21b, Point A remains fixed whilst the leading end of the lumen rolls out. Since the Cyclops does not change in overall length the trailing end of outside diameter rolls in as depicted. It will be apparent that the shaft translates to the right twice as far as the Cyclops. This, of course, is exactly the motion of a caterpillar track. From this point of view a Cyclops could be considered as a three dimensional caterpillar track. Since points A and B on the Cyclops do not move relative to their corresponding positions on the shaft and the fixed surface there is no frictional resistance to the translation of the shaft. In Fig. 21c the Cyclops has translated to the right by approximately its own length. The material which had originally formed the inner tube has rolled out to become the outer tube and vice versa. In other words the Cyclops has turned inside out. Since the inner tube of the Cyclops is in a twisted configuration and since the point B remains in contact with the same point on the shaft the shaft rotates about its axis as depicted by arrow C (in this instance approx. 120°). In order to obtain this translation the resistance required to be overcome is that generated as the leading and trailing ends of the Cyclops deform as they roll out and roll in respectively.

## Effects of an introduced member

Assume that the Cyclops in Fig. 22 has a 180° twist and is filled with a fluid under pressure. The lumen is closed by the action of the twist. As the shaft enters the Cyclops the pliable nature of the material of the Cyclops allows it to envelop the leading edge of the shaft as shown in Fig. 22b. As can be seen the effective volume of the Cyclops decreases. There will be a resulting increase of the fluid pressure causing the lumen to exert a greater pressure on the shaft. As the shaft proceeds through the Cyclops, see Fig. 22c, the pressure increases to it's maximum. ($P1V1=P2V2$). If it is not desirable that there be such a pressure increase then the supply of fluid could be controlled by a pressure regulator.

Effects of the tube preform shape

Consider the tube preform shown in Fig. 25a. The lower portion defines a circular elbow with an upper section configured as a plain cylinder. If the cylindrical section is inverted as indicated, with or without a twist, and the free ends of the preform conjoined a basic Cyclops is formed. The elbow section must wrinkle up in order to lie within the plain cylinder as shown in Fig. 25b. As previously, the introduction of a pressurised fluid into the enclosed cavity formed will cause the elbow section to collapse forming a closed lumen and the cylindrical section to inflate, see Fig. 25c. The plain cylinder, being on the outside of the structure, will determine the shape of the inflated Cyclops. The Cyclops will be in force balance. If a force is applied to the lower end of the lumen the net force on the lumen will cause the Cyclops to translate. The upper portion of the lumen will roll out and the lower end of the cylindrical wall will roll in, Fig. 25d. Since the outside wall of the Cyclops is now made up of part of the original plain cylinder and part of the elbow section the inflation pressure will cause the Cyclops to take on the form of this composite profile, the Cyclops will appear to bend as it translates. Figs 25d shows the Cyclops completely inverted. All of the elbow section forms the outer wall and all of the plain cylindrical section forms the inner tube. As such the Cyclops has take on the form of the elbow section. It will be noted that lumen material follows the shortest line between the ends of the Cyclops. For simplicity of illustration the Cyclops has been represented as translating in two space. It will be apparent that if the preform were "sculpted" or moulded such that its axis were three dimensional then as the Cyclops translated the path of translation would follow a three dimensional path. It will also be appreciated that the preform need not be of a regular cross section. Variations in tube diameter along it's length is possible.

Referring to Figs. 26(a) to 26(d) there is illustrated the roll-out or eversion of a pre-shaped device, in this case an introducer device 100. The device 100 is in this case

The invention is not limited to the embodiments hereinbefore described which may be varied in detail.

5. A device as claimed in any of claims 1 to 4 wherein the sleeve is biassed into the non linear shape.

6. A device as claimed in any of claims 1 to 5 wherein the sleeve is sculpted or formed into the non linear shape.

7. A device as claimed in any preceding claim wherein the sleeve is turned axially back on itself to define an outer sleeve section and a twisted inner sleeve section.

8. A device as claimed in any preceding claim wherein the sleeve sections define a continuous endless track which may be advanced by engaging an object in the lumen.

9. A device as claimed in any preceding claim including a guide collar for locating relative to a datum, a sleeve section being movable relative to the collar on engaging an object into the lumen and/or on passage of an object through the lumen.

10. A device as claimed in claim 9 wherein the free ends of the sleeve are joined to the collar.

11. A device as claimed in any preceding claim including an inflation port for inflation of the enclosed chamber between the sleeve sections.

12. A device as claimed in any preceding claim including guide means through which the sleeve and/or an object is advanced.

13. A device as claimed in claim 12 wherein the guide means includes a ring means for placing in a body opening or incision through which the sleeve and/or an object is advanced.

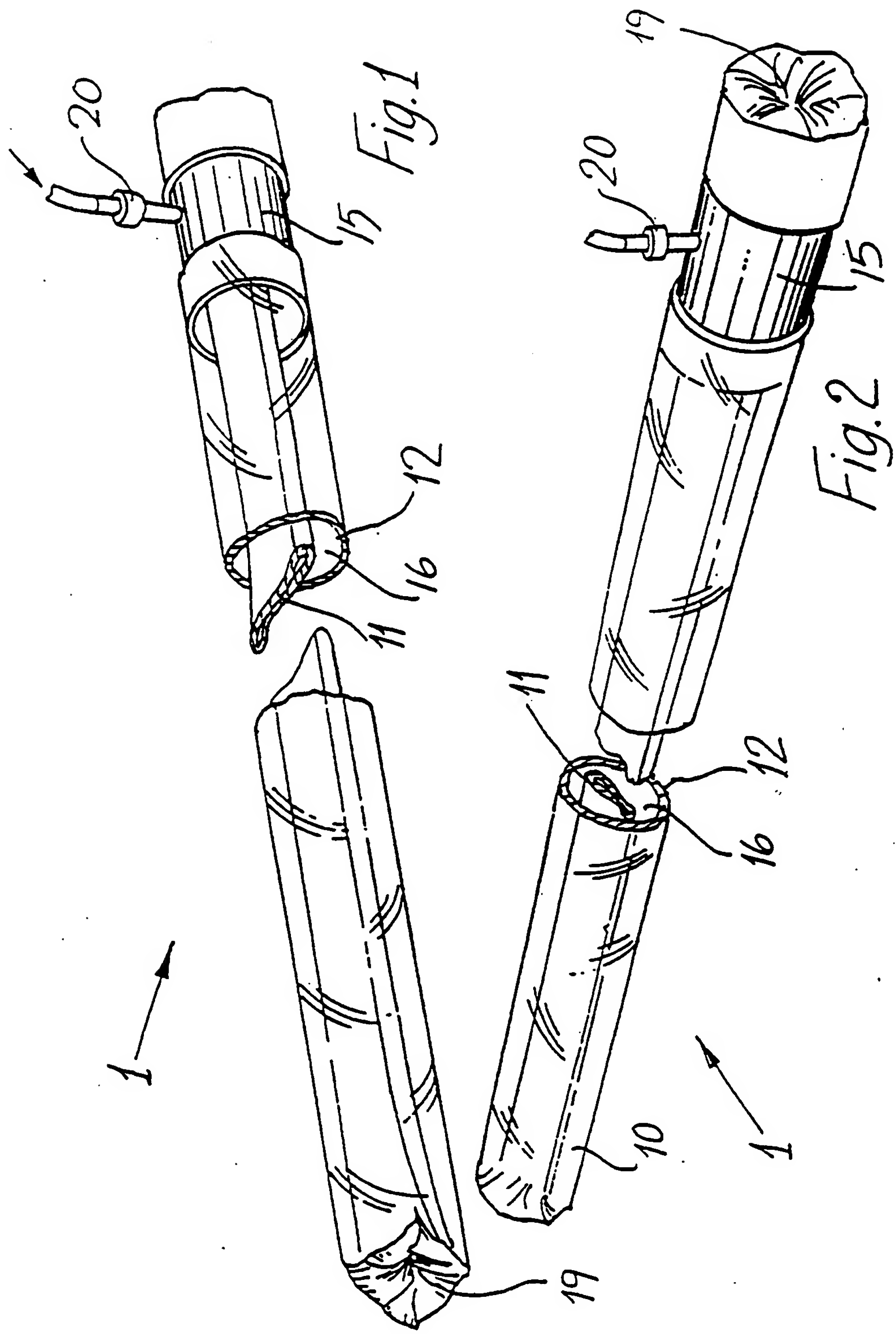


Fig.1
Fig.2
20
15
12
16
11
1
10
19

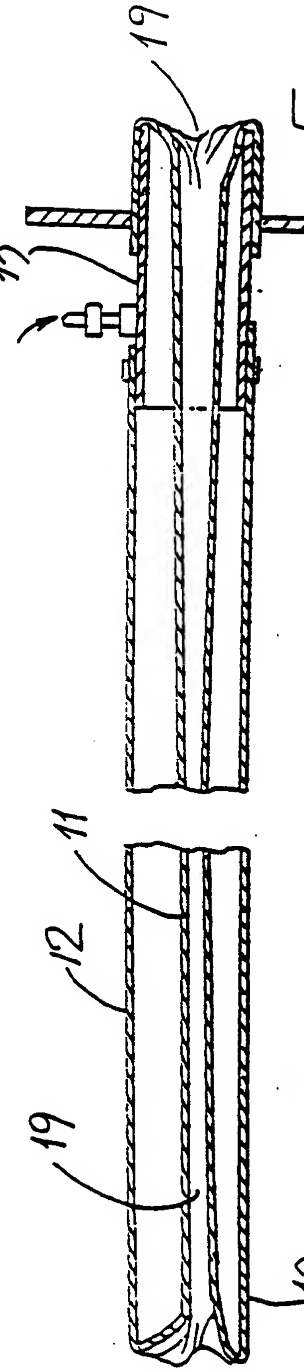



Fig.3

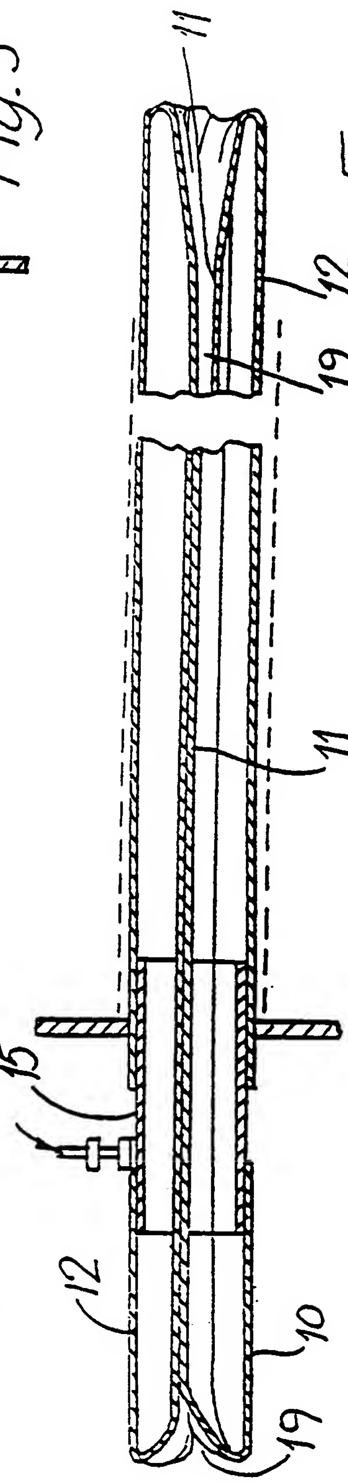



Fig.4

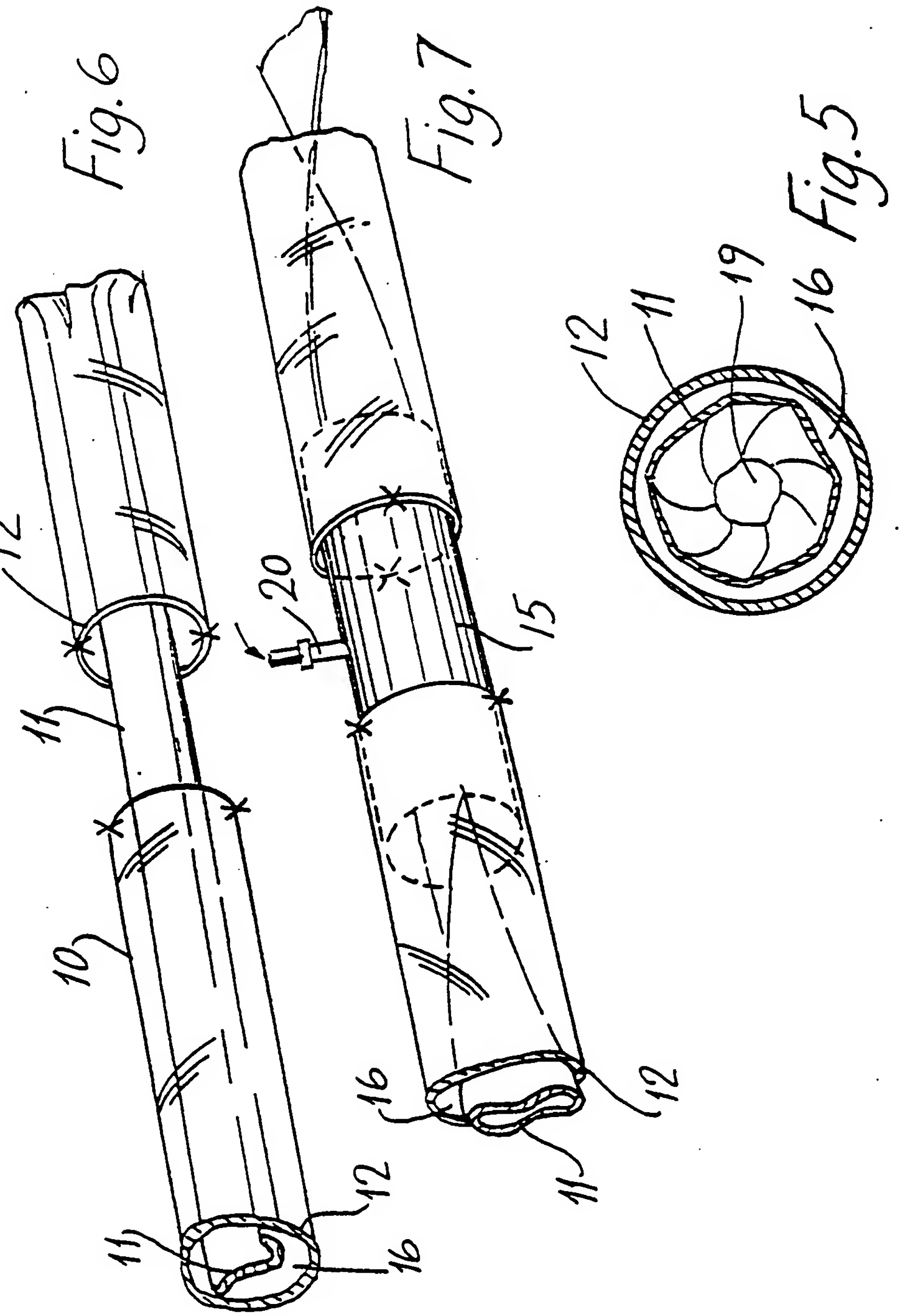


Fig.6
Fig.7
Fig.5
12
11
10
16
20
15
19

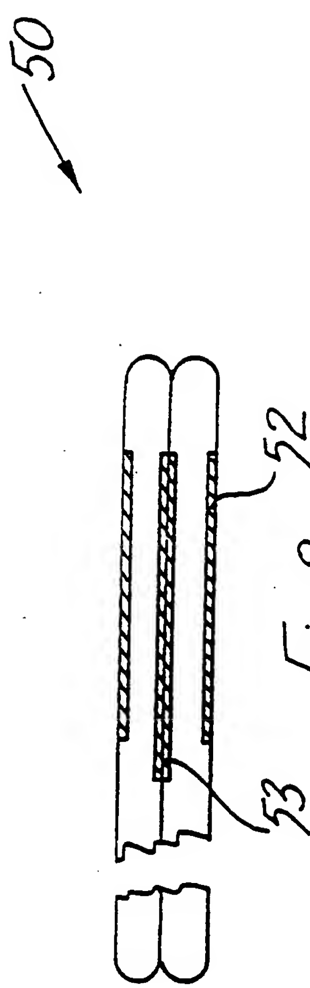



Fig.8

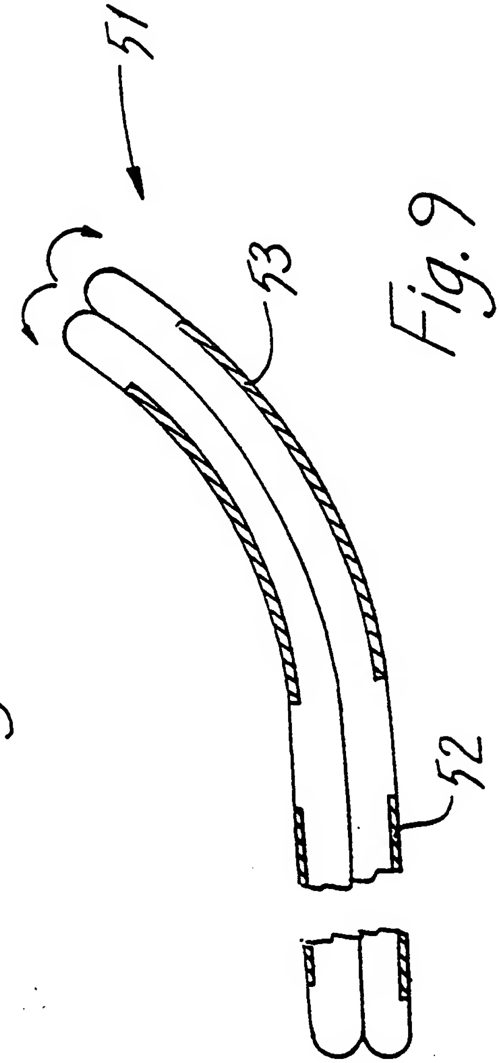



Fig.9

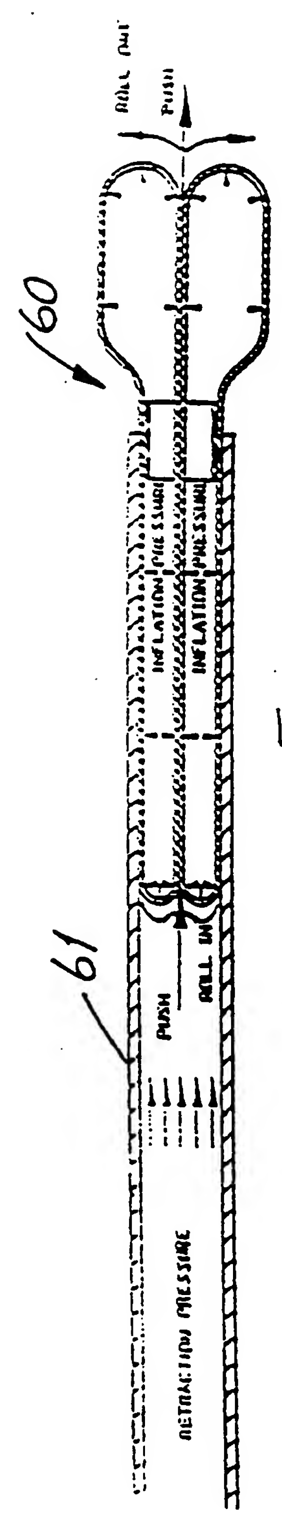

ROLL OUT
PUSH
60
INFLATION PRESSURE
INFLATION PRESSURE
61
PUSH
ROLL IN
RETRACTION PRESSURE

Fig.10

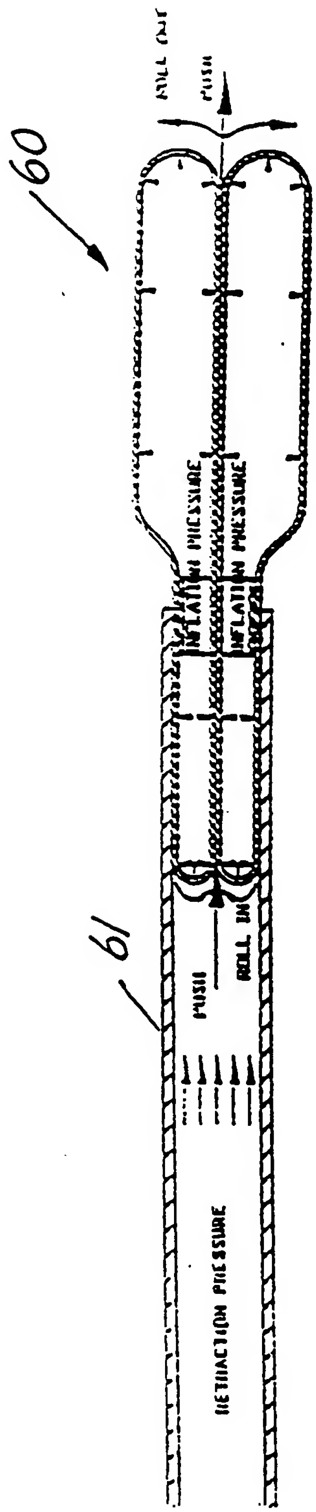

ROLL OUT
PUSH
60
INFLATION PRESSURE
INFLATION PRESSURE
61
PUSH
ROLL IN
RETRACTION PRESSURE

Fig.11

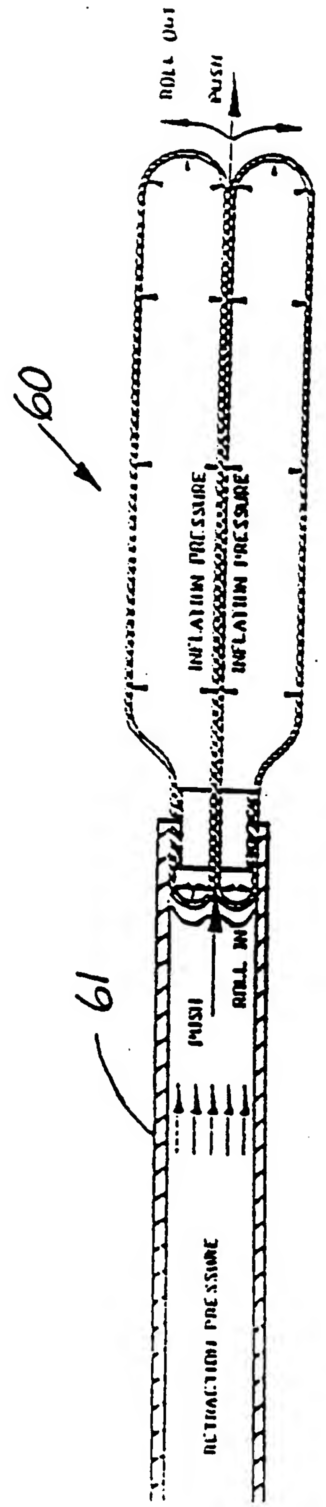

ROLL OUT
PUSH
60
INFLATION PRESSURE
INFLATION PRESSURE
PUSH
ROLL IN
61
RETRACTION PRESSURE

Fig.12

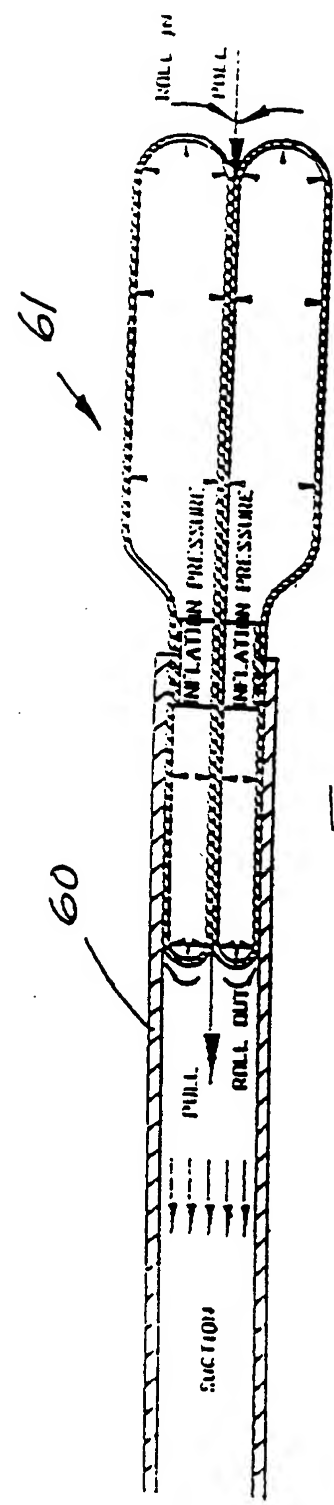

ROLL IN
PULL
61
INFLATION PRESSURE
INFLATION PRESSURE
60
PULL
ROLL OUT
SUCTION

Fig.13

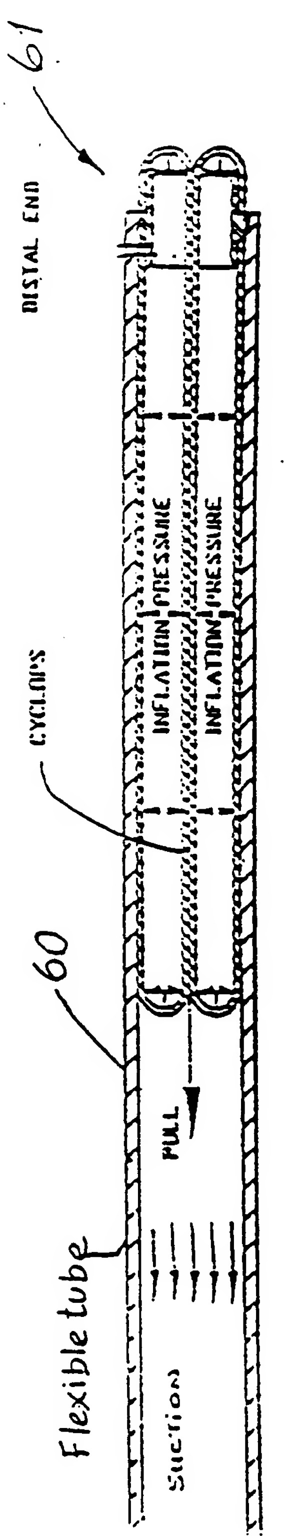



Fig.14

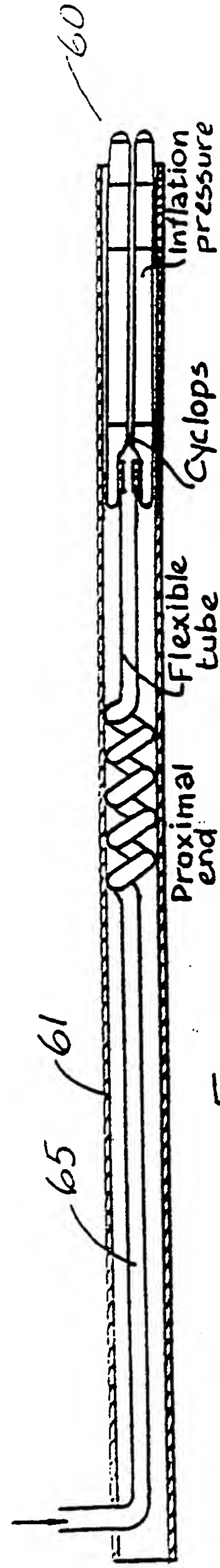



Fig.15

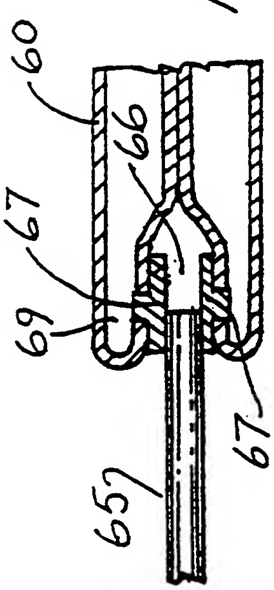



Fig.16

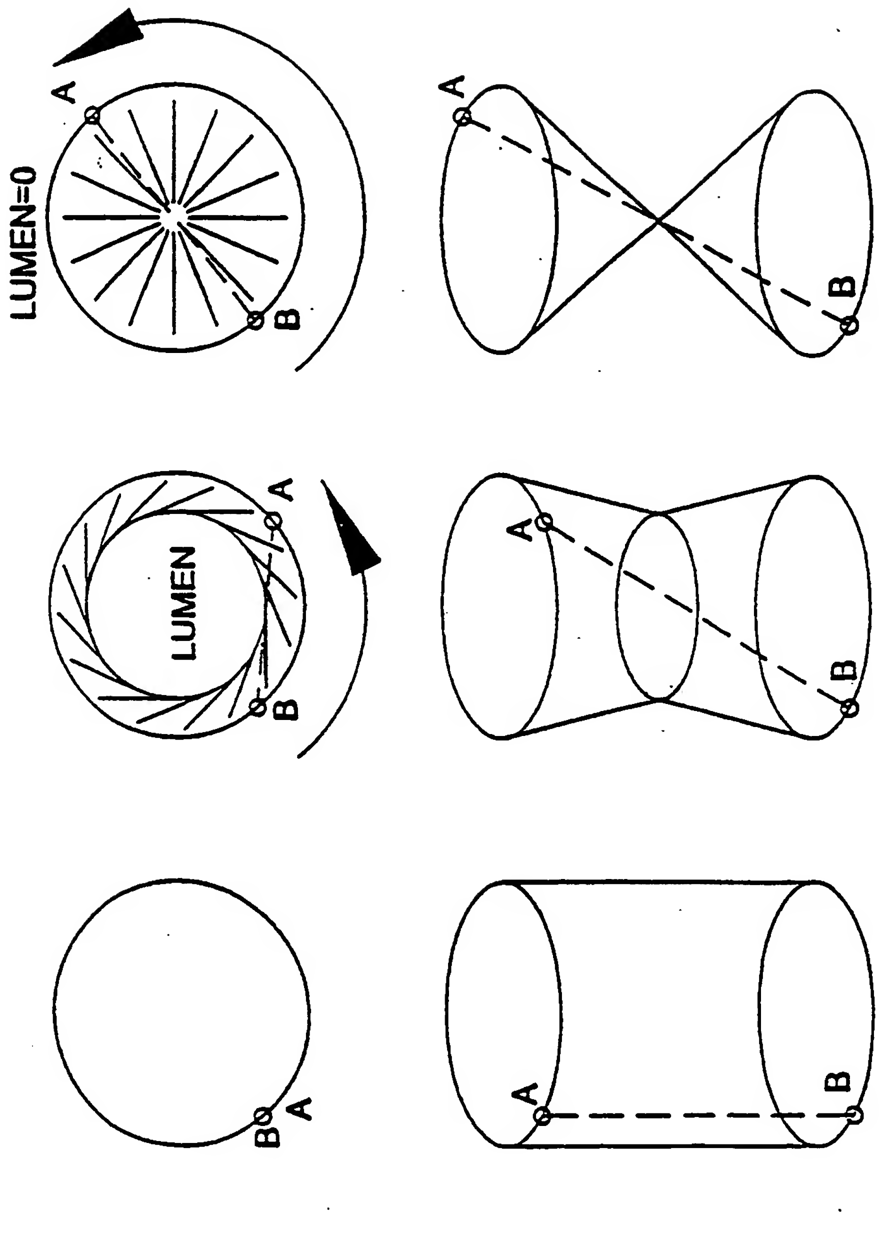



Fig. 17 The Twisted Tube

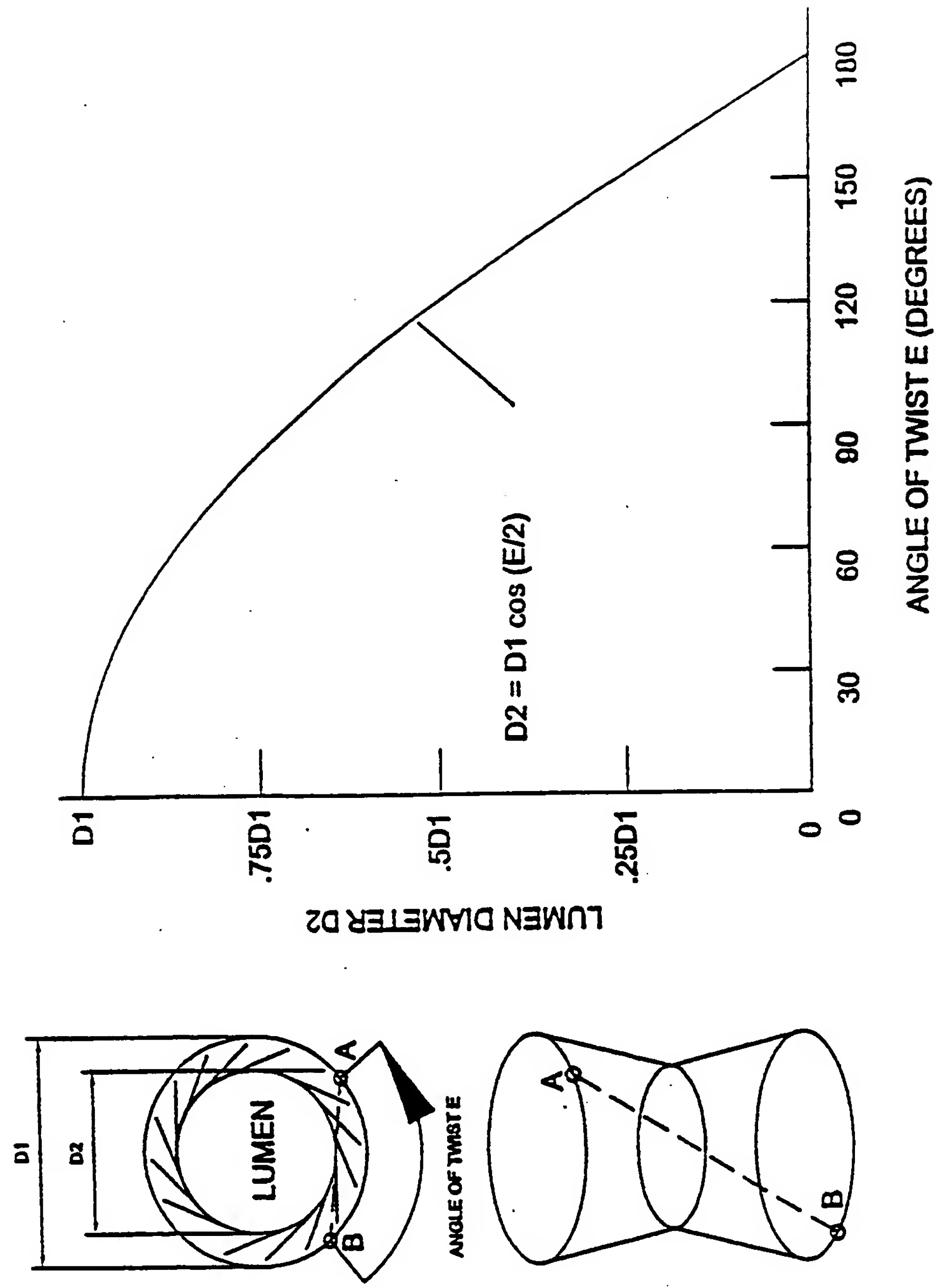



Fig.18a Angle of twist vs lumen

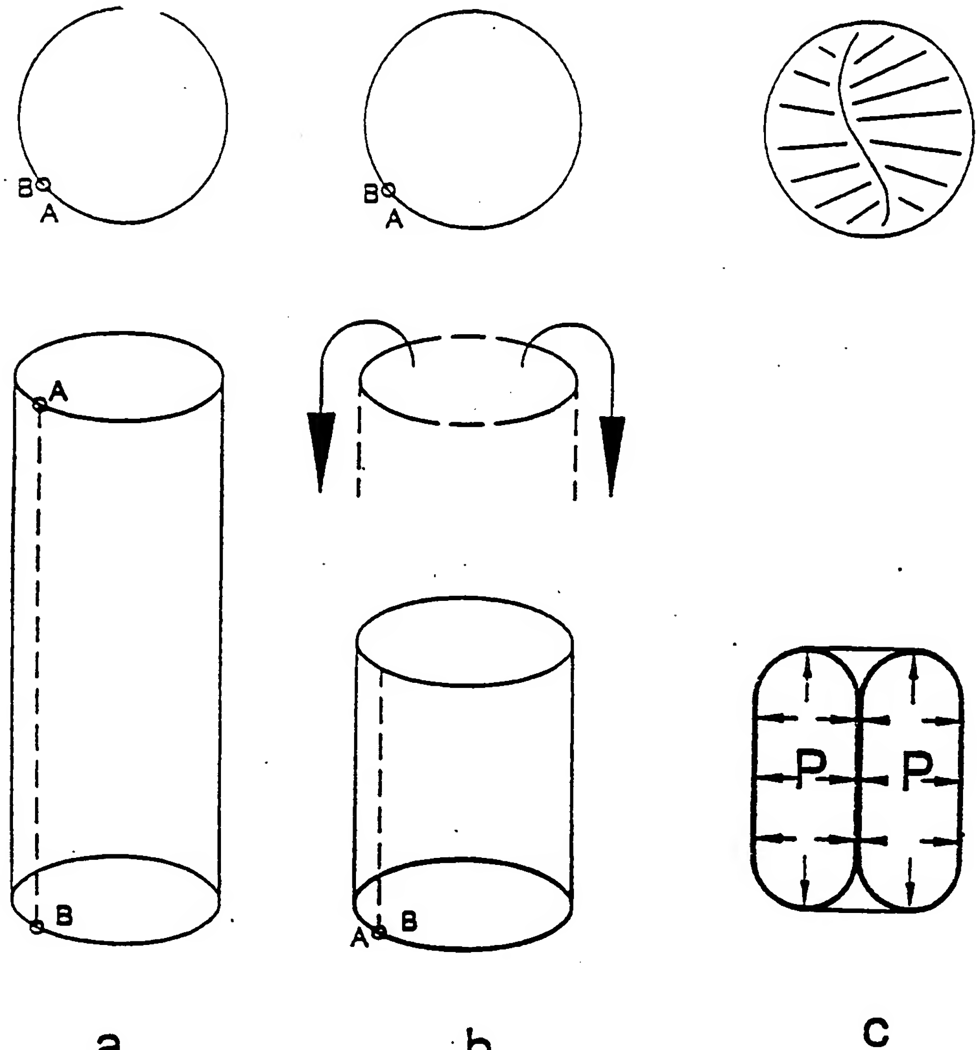



Fig.19 Twin Walled vessel under internal pressure

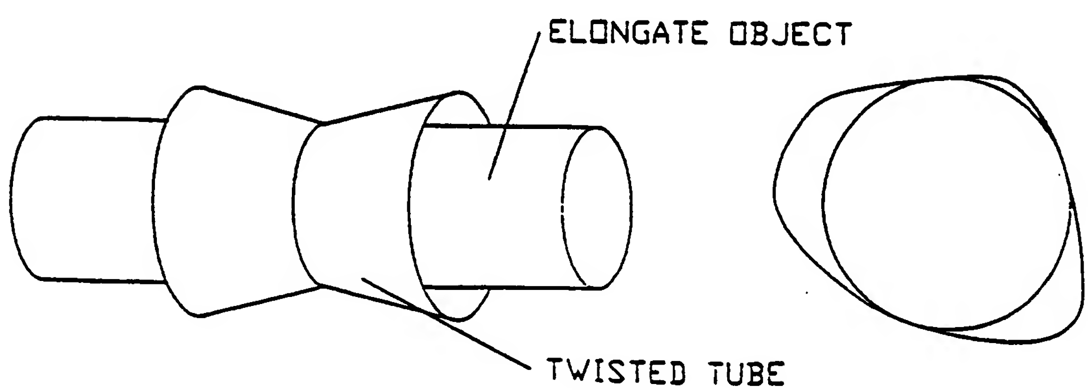



Fig.18b Twisted tube with elongate object passing therethrough

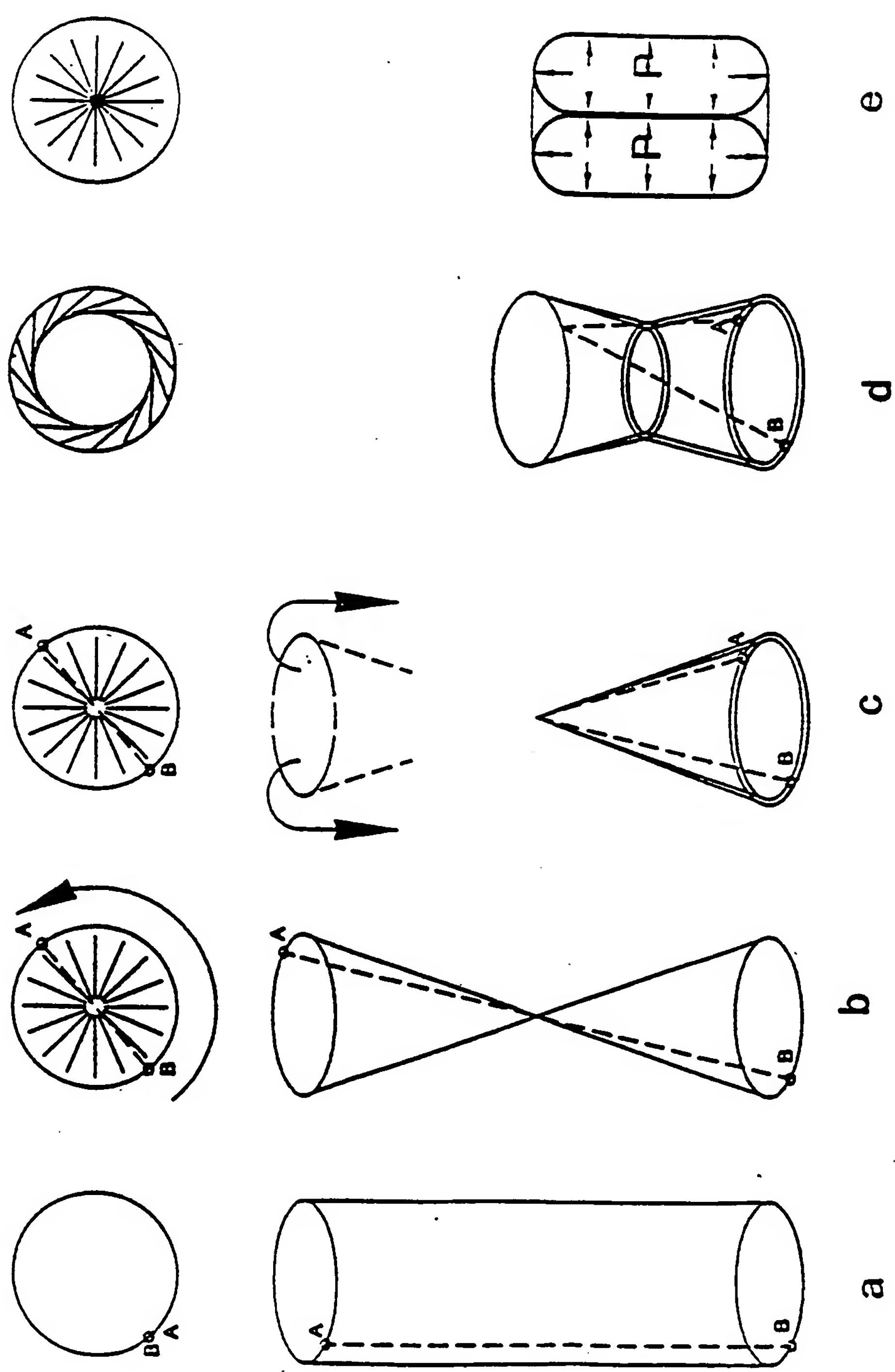



Fig.20 Twin walled tube with twist subject to internal pressure

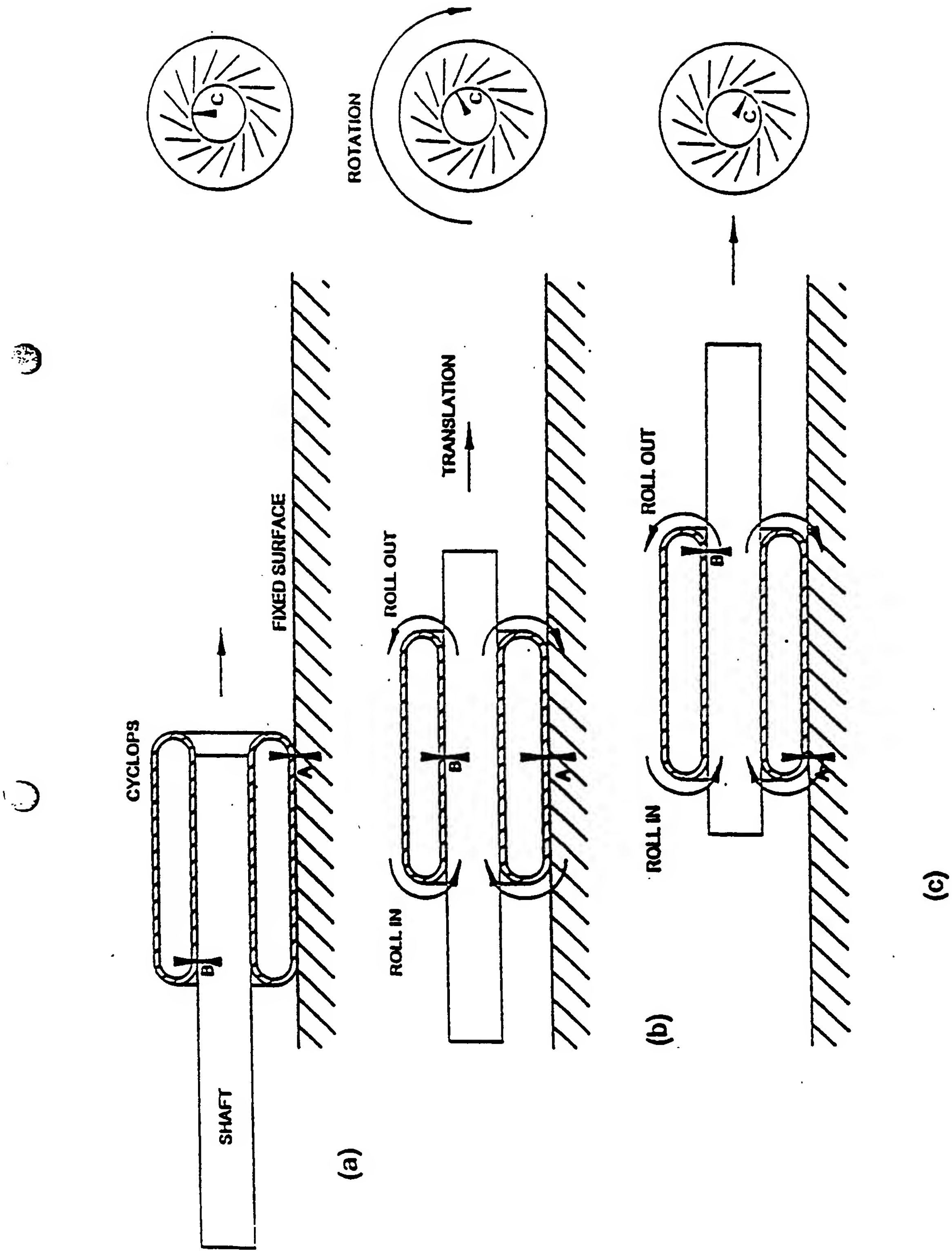



Fig.21 Translation of a shaft within a Cyclops

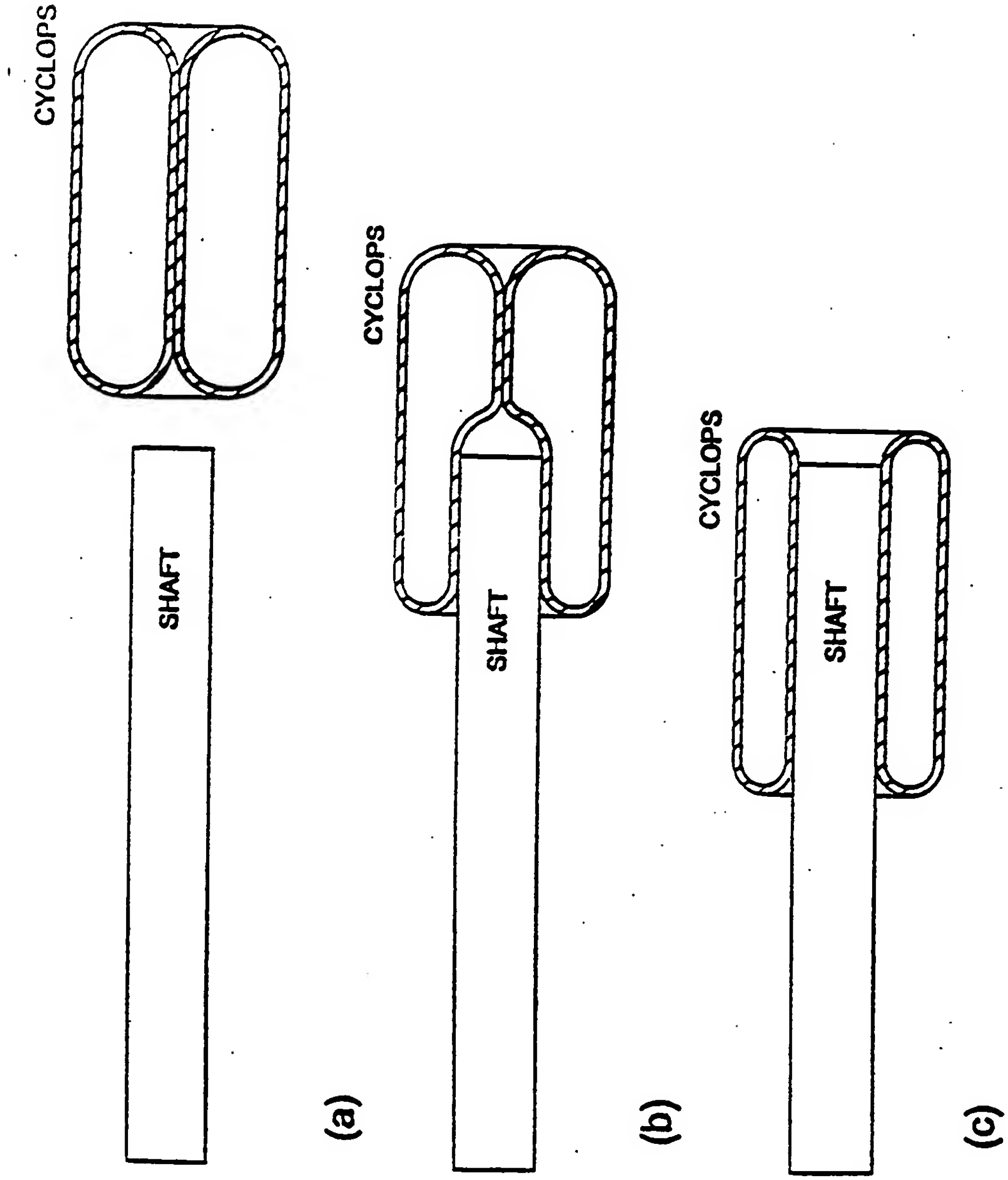



Fig.22 The deformation of a Cyclops as a shaft enters and translates

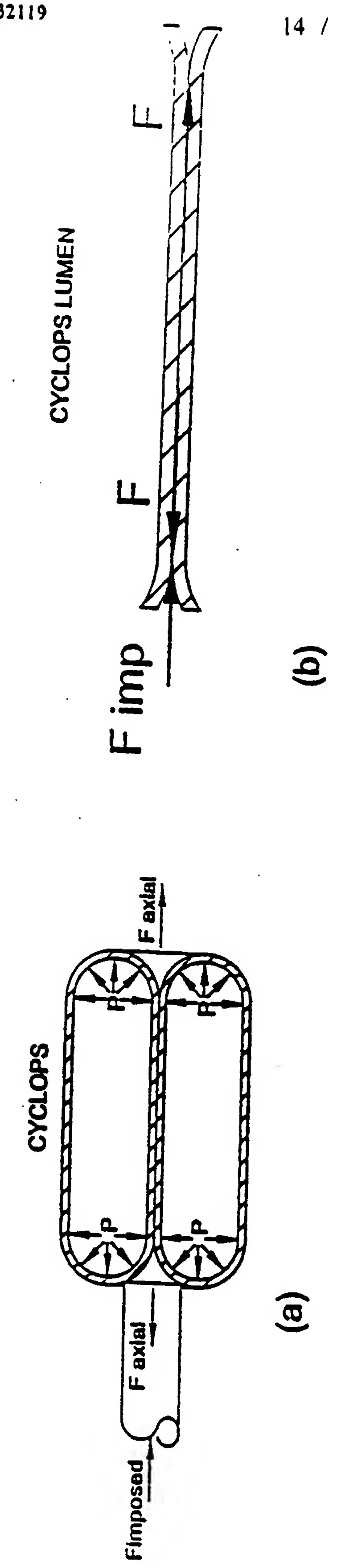



Fig 23 Forces acting on Cyclops lumen due to axial component of pressure

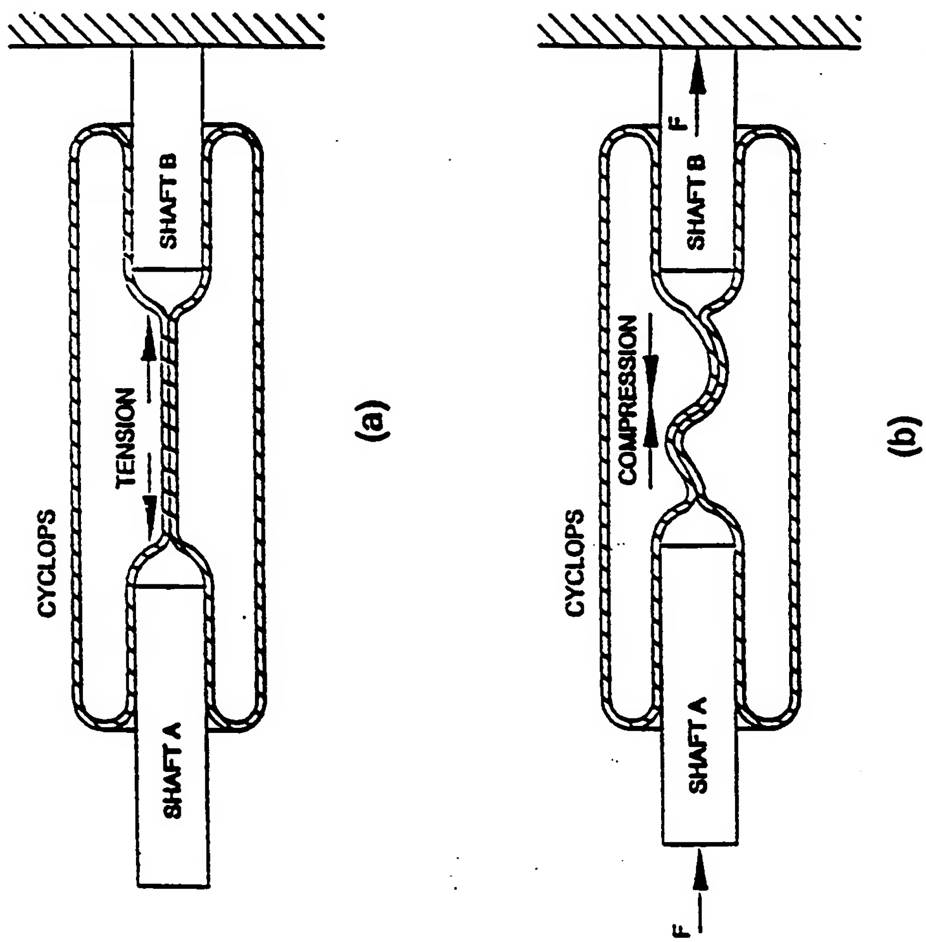



Fig.24 Stiffness of Cyclops lumen

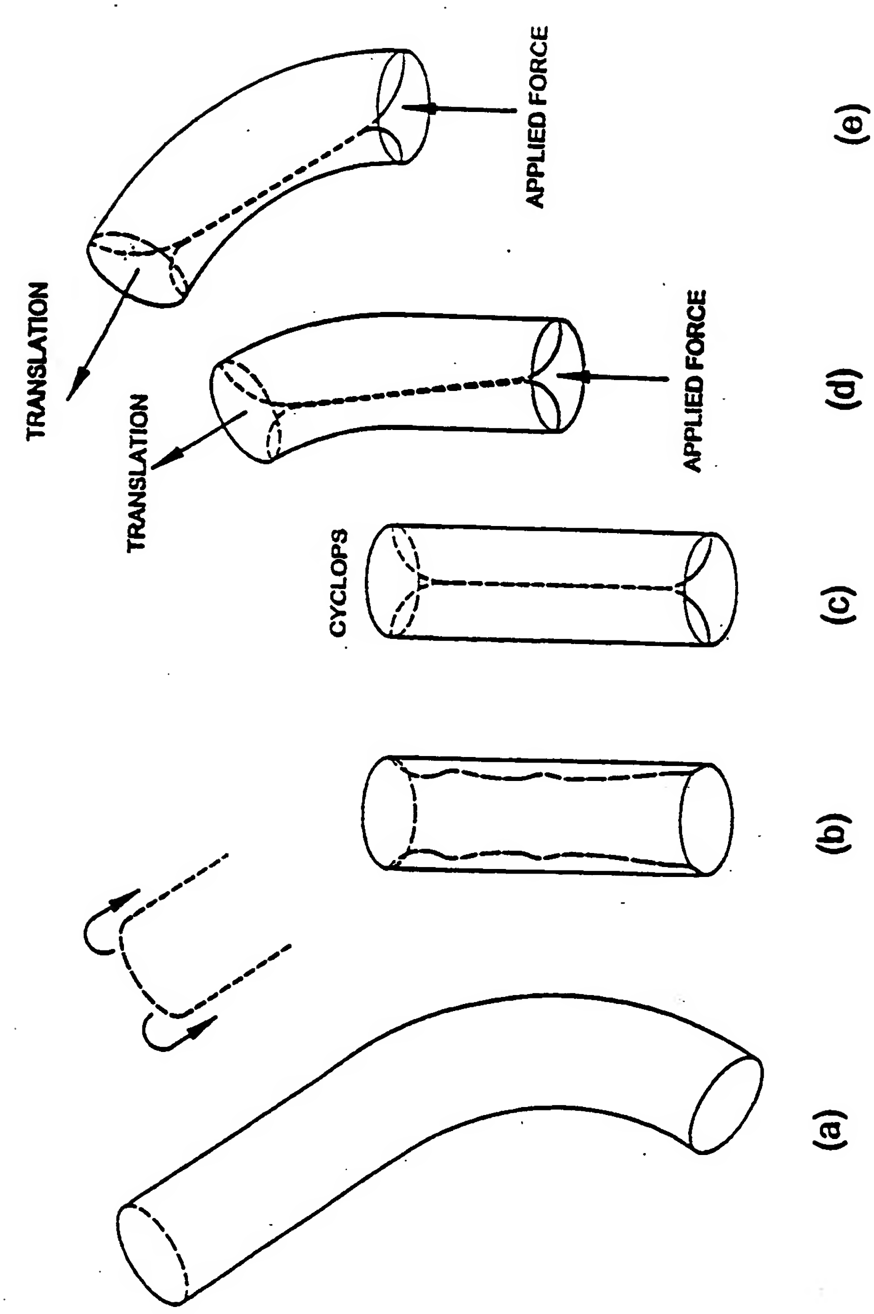
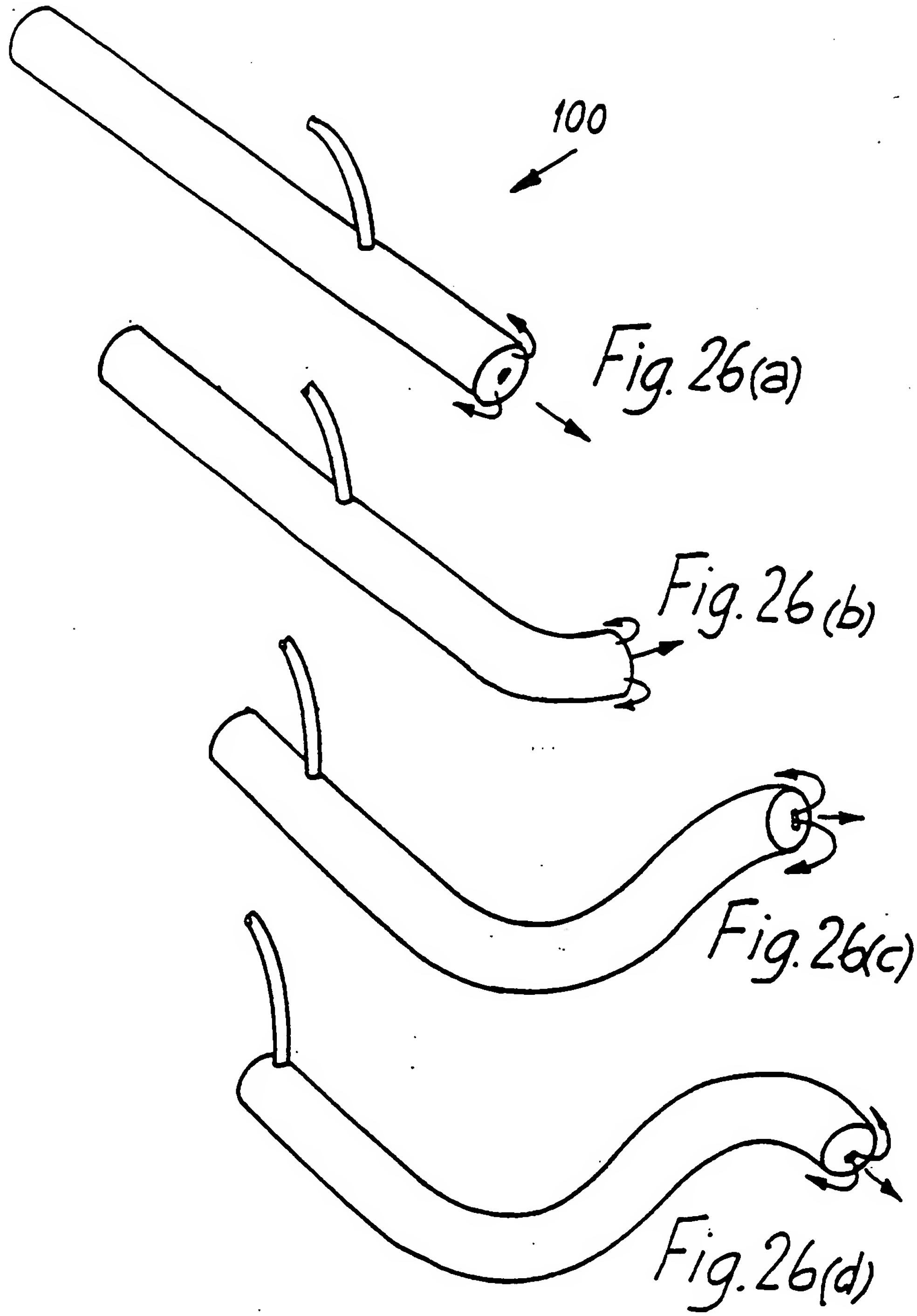



Fig.25 Effects of tube preform shape


100
Fig. 26(a)
Fig. 26(b)
Fig. 26(c)
Fig. 26(d)

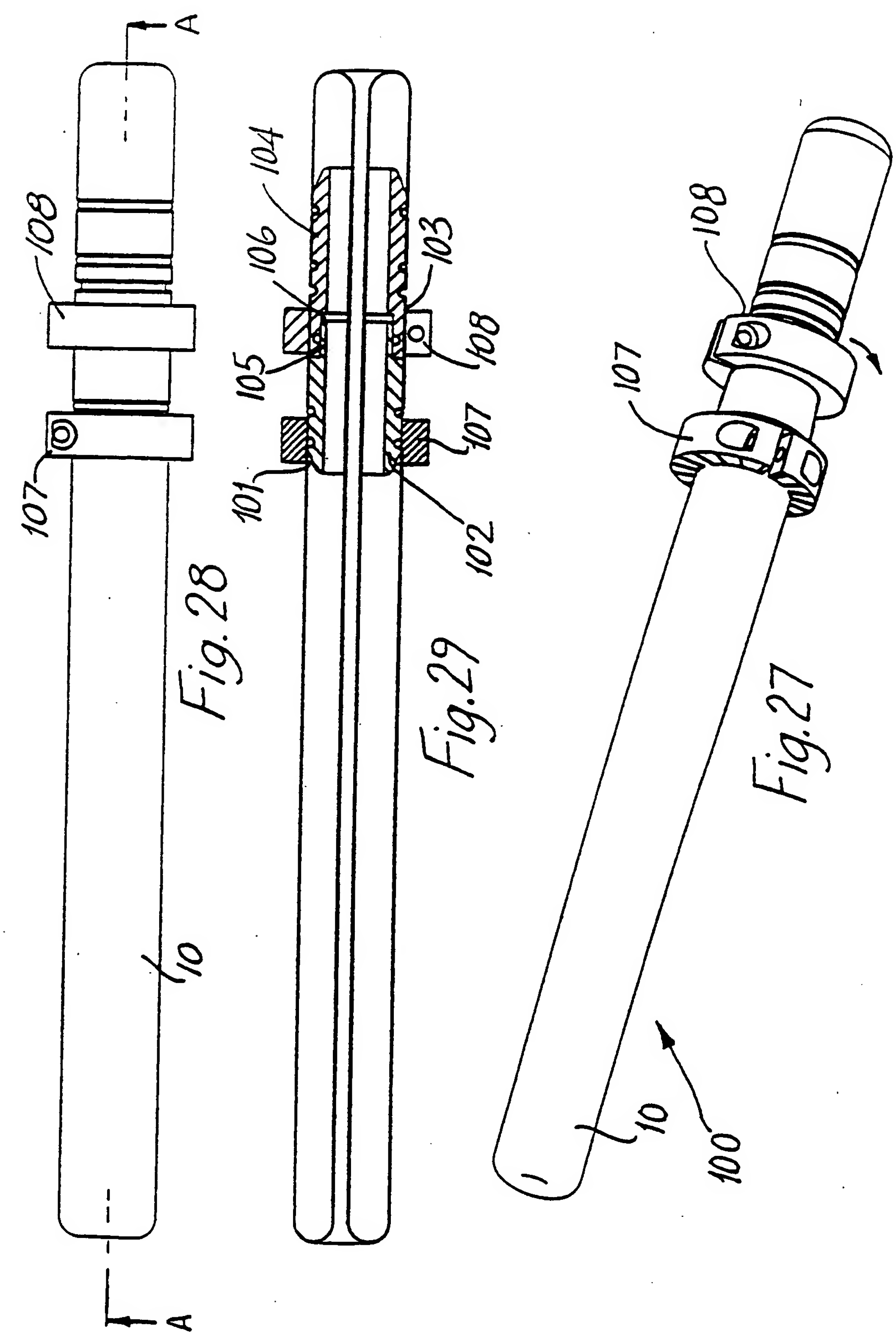



Fig.28

Fig.29

Fig.27

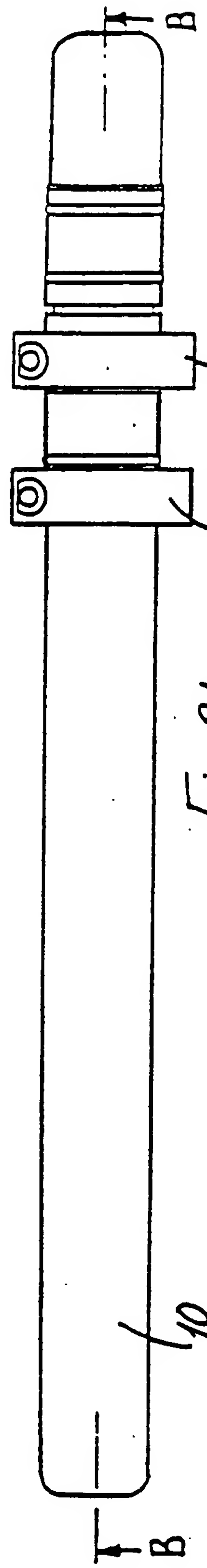



Fig.31

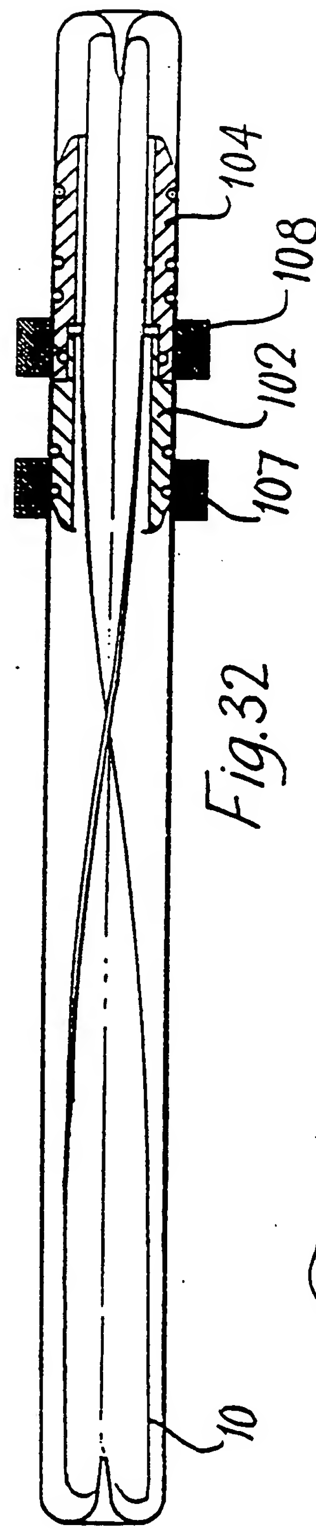



Fig.32

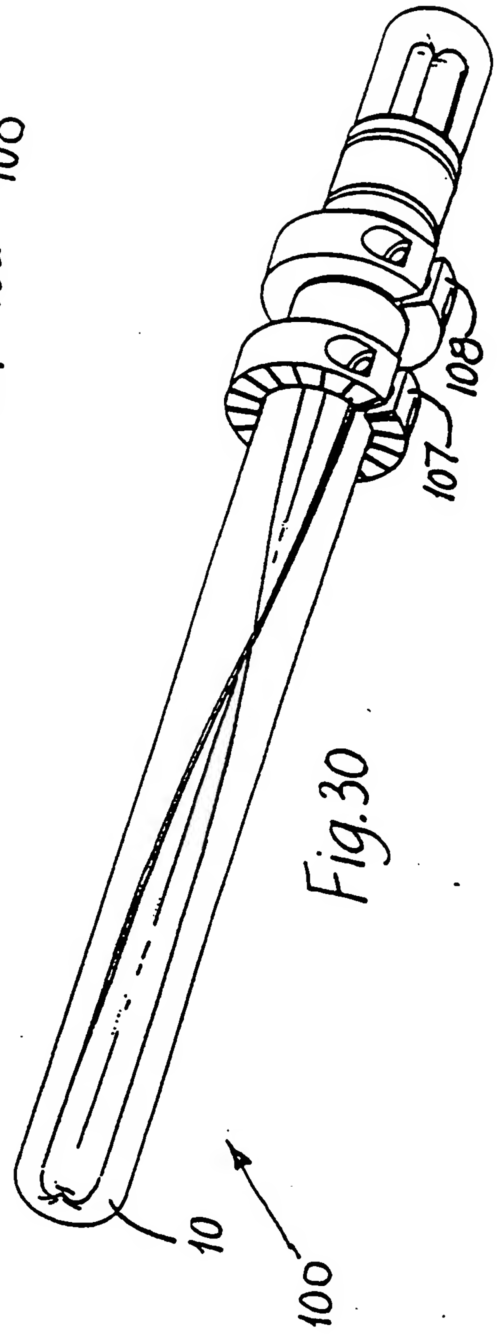



Fig.30